IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ENDO USA, INC. and
ENDO OPERATIONS LIMITED,

*Plaintiff*s,

v.

BAXTER HEALTHCARE CORPORATION,

Defendant.

Case No. 1:25-cv-2365

COMPLAINT

Plaintiffs Endo Operations Limited ("EOL") and Endo USA, Inc. ("Endo USA"), (collectively, "Plaintiffs" or "Endo"), for their complaint against Defendant Baxter Healthcare Corporation ("Baxter"), allege as follows:

NATURE AND SUMMARY OF THIS ACTION

1. This is an action for declaratory judgment of patent infringement of U.S. Patent Nos. 11,071,719 (the "'719 patent"), 11,207,280 (the "'280 patent"), and 12,133,837 (the "'837 patent") (collectively, "the Patents-in-Suit") arising under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 271 against Defendant Baxter. This action relates to Baxter's Epinephrine in 0.9% Sodium Chloride Injection product ("Baxter's Epinephrine Bags"), which the U.S. Food and Drug Administration (FDA) recently approved to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock, and that, on information and belief, Baxter is in the process of preparing to launch in the United States. Baxter's commercial manufacture, importation, use, offering for sale, or sale within the United States will infringe claims of each of the Patents-in-Suit.

THE PARTIES

2. EOL is an Irish company with offices located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

3. Endo USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 9 Great Valley Parkway, Malvern, Pennsylvania 19355.

4. On information and belief, Baxter is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

5. On information and belief, Baxter is a healthcare company and pharmaceutical manufacturer that develops, manufactures, markets and/or distributes pharmaceutical products around the United States, including in this judicial district.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq. and this Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. This Court has personal jurisdiction over Baxter at least because, upon information and belief, has a principal place of business in the state of Illinois.

8. This Court has personal jurisdiction over Baxter at least because Baxter has continuous and systematic contacts within this judicial district. On information and belief, Baxter develops, manufactures, seeks approval for, and sells certain FDA-approved pharmaceutical products that are regularly marketed and sold in Illinois.

9. On information and belief, Baxter has availed itself of the jurisdiction of this Court in prior cases. *See, e.g.*, *Baxter Healthcare Corp., et al. v. Sagent Pharms., Inc.,* CA No.

15-2076 (N.D. Ill.); *Baxter Healthcare Corp., et al. v. Fresenius Medical Care Holdings, Inc.*, CA No. 08-2389 (N.D. Ill.).

10. On information and belief, Baxter has previously been sued in this judicial district and has not challenged personal jurisdiction and venue. *See, e.g., Millenium Biologix, LLC v. Baxter Healthcare Corp. et al.*, CA No. 13-3084 (N.D. Ill.).

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b) at least because, on information and belief, Baxter has a regular and established place of business in this juridical district.

THE PATENTS-IN-SUIT

12. The ’719 patent, titled “Epinephrine Compositions and Containers,” was duly and legally issued by the United States Patent and Trademark Office on July 27, 2021. A true and correct copy of the ’719 patent is attached as Exhibit A.

13. EOL is an exclusive licensee of the ’719 patent and has all substantial rights to the ’719 patent. EOL has the ability and proper standing to enforce the ’719 patent. EOL has granted an exclusive sublicense in the ’719 patent to its affiliate, Endo USA.

14. The ’280 patent, titled “Epinephrine Compositions and Containers,” was duly and legally issued by the United States Patent and Trademark Office on December 28, 2021. A true and correct copy of the ’280 patent is attached as Exhibit B.

15. EOL is an exclusive licensee of the ’280 patent and has all substantial rights to the ’280 patent. EOL has the ability and proper standing to enforce the ’280 patent. EOL has granted an exclusive sublicense in the ’280 patent to its affiliate, Endo USA.

16. EOL listed the ’280 patent in the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) for New Drug Application (“NDA”) No. 215875 on May 10, 2023.

17. The ’837 patent, titled “Epinephrine Compositions and Containers,” was duly and legally issued by the United States Patent and Trademark Office on November 5, 2024. A true and correct copy of the ’837 patent is attached as Exhibit C.

18. EOL is an exclusive licensee of the ’837 patent and has all substantial rights to the ’837 patent. EOL has the ability and proper standing to enforce the ’837 patent. EOL has granted an exclusive sublicense in the ’837 patent to its affiliate, Endo USA.

19. EOL listed the ’837 patent in the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) for NDA No. 215875 on November 6, 2024.

EOL’S ADRENALIN® PRODUCTS

20. EOL is the holder of NDA No. 204200 for Adrenalin® brand epinephrine 1 mg/mL single-dose vials, approved on December 7, 2012 (the “Adrenalin® single-dose vials”). EOL is the holder of NDA No. 204640 for Adrenalin® brand epinephrine 30 mg/30 mL multi-dose vials, approved on December 18, 2012 (the “Adrenalin® multi-dose vials,” and together with the Adrenalin® single-dose vials, the “Adrenalin® vials”). Adrenalin® vials were the first FDA-approved epinephrine injection product for use in a clinical setting available in the United States. Adrenalin® vials are indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock and also for the emergency treatment of allergic reactions (Type 1), including anaphylaxis. (*See* Exhibit D (Adrenalin® label (Oct. 2023)) at 1.)

21. EOL is the holder of NDA No. 215875 for Adrenalin® in five dosage strengths: 2 mg (8 µg/mL epinephrine), 4 mg (16 µg/mL epinephrine), 5 mg (20 µg/mL epinephrine), 8 mg (32 µg/mL epinephrine), and 10 mg (40 µg/mL epinephrine), each of which is provided in 250 mL infusion bags (hereafter, the “Adrenalin® bags”). Adrenalin® bags are indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock. (*See* Exhibit D (Adrenalin® label (Oct. 2023)) at 1.)

22. Epinephrine is involved in various regulatory processes within the body, including regulation of heart beat, blood pressure, airway resistance, and energy metabolism. Septic shock is a life-threatening medical condition that is characterized by a severe drop in blood pressure. Septic shock is the last and most dangerous stage of sepsis. Treatments for septic shock include administration of vasopressors, such as epinephrine.

23. Prior to EOL's new product, epinephrine was marketed as a concentrated form for injection (1 mg/mL). In its concentrated form, epinephrine must be diluted with a specific diluent such as dextrose or dextrose with sodium chloride when used to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock. These commercially available epinephrine formulations lack storage stability and must be discarded the same day after reconstitution when stored at room temperature. Moreover, these concentrated epinephrine formulations carry a risk of dilution errors, and the resulting diluted solutions are prone to microbial contamination and have limited shelf life due to reduced chemical stability.

24. There have been multiple efforts to develop a stable, ready-to-use epinephrine formulation that does not require dilution before use, but these efforts failed due to the sensitivity of epinephrine. Epinephrine in aqueous solution deteriorates (by oxidation) rapidly with exposure to air or light. Epinephrine solutions may also lose potency as a result of racemization of the biologically active R-isomer to the biologically inactive S-isomer. Efforts to overcome some of these drawbacks included chemical modifications of the epinephrine solutions. Use of certain chemicals with these solutions, however, have resulted in severe allergic reactions.

25. EOL's development partner, Nevakar Injectables, Inc., set out to solve these drawbacks and through considerable research and development invented an improved stable, low

concentration, ready-to-administer substantially antioxidant free epinephrine formulation. These efforts led to a series of issued patents including the '719, '280, and '837 patents.

26. Endo USA sells both Adrenalin® vials and Adrenalin® bags.

27. Adrenalin® bags are the first FDA-approved manufacturer-prepared epinephrine premixed intravenous (IV) bag.

BAXTER'S READY-TO-USE EPINEPHRINE BAG PRODUCTS

28. Baxter filed NDA No. 218475 under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act ("FDCA") on September 29, 2023, for epinephrine solution in bags. FDA approved that NDA on February 28, 2025 as Baxter's Epinephrine Bags. Exhibit E (Approval Letter) at 1.

29. Unless enjoined by this Court, Baxter's Epinephrine Bags will be sold as 16 mg epinephrine in 0.9% sodium chloride injection (64 µg/mL) in bags. (Exhibit D (Label) at Section 11).

30. Baxter's Epinephrine Bags contain 64 µg/mL of epinephrine, 9.0 mg/mL of sodium chloride, 0.05 mg/mL of sodium metabisulfite, 0.032 mg/mL of edetate disodium (EDTA), sodium hydroxide "to adjust pH," hydrochloric acid "to adjust pH," and water for injection. (*See* Exhibit D (Label) at Section 11.) The pH of Baxter's Epinephrine Bags is 3.4 to 4.5. (*See* Exhibit D (Label) at Section 11.)

COUNT I
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '719 PATENT)

31. Endo re-alleges and incorporates Paragraphs 1-30 as if fully set forth herein.

32. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

33. There is an actual case of controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

34. On information and belief, Baxter will engage immediately and imminently in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Baxter's Epinephrine Bags which will constitute infringement of at least claim 1 of the '719 patent, both directly under 35 U.S.C. § 271(a) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

35. Claim 1 of the '719 patent reads as follows:

> A method of producing a storage stable ready-to-inject epinephrine composition, comprising:
>
> combining an aqueous pharmaceutically acceptable carrier with epinephrine in an amount such that the epinephrine is present in the ready-to-inject epinephrine composition at a concentration of equal or less than 0.07 mg/mL;
>
> wherein substantially all of the epinephrine is an R-isomer;
>
> wherein the aqueous pharmaceutically acceptable carrier has dissolved oxygen in an amount of equal or less than 2 ppm;
>
> adjusting the pH of the ready-to-inject epinephrine composition to a pH of between 3.0-4.7;
>
> including into the ready-to-inject epinephrine composition a metal ion chelator selected from the group consisting of EDTA, EGTA, and diethylenetriaminepentaacetic acid, and wherein the metal ion

> chelator is present in the composition at a concentration of between about 1 and 50 mcg/mL;
>
> packaging the ready-to-inject epinephrine composition into a container under an inert gas;
>
> sterilizing the ready-to-inject epinephrine composition; and
>
> wherein the ready-to-inject epinephrine composition is substantially antioxidant-free and has, after storage of at least one month, total impurities of equal or less than 0.7% and equal or less than 4% S-isomer content.

36. Baxter's Epinephrine Bags are storage stable ready-to-inject epinephrine compositions, produced by Baxter or for Baxter. (*See* Exhibit D (Label) at Section 2.1; Exhibit E (Approval Letter) at 2.)

37. Baxter's Epinephrine Bags contain an aqueous pharmaceutically acceptable carrier with epinephrine in an amount such that the epinephrine is present in the ready-to-inject epinephrine composition at a concentration of equal or less than 0.07 mg/mL. (*See* Exhibit D (Label) at Section 11.)

38. On information and belief, Baxter's Epinephrine Bags contain epinephrine wherein substantially all of the epinephrine is an R-isomer. Baxter's Epinephrine Bags contain 64 µg/mL of epinephrine. (*See* Exhibit D (Label) at Section 11.) Baxter's Epinephrine Bags are USP compliant. (*See* Exhibit D (Label) at Section 11; Exhibit E (Approval Letter) at 3.) The USP monograph for epinephrine requires an epinephrine assay of 90-115%. Epinephrine is only biologically active in the R-isomer, and the S-isomer is biologically inactive. (*See* Exhibit A ('719 patent) at 2:1-3.) To achieve the dosage strength described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer.

39. On information and belief, Baxter's Epinephrine Bags contain an aqueous pharmaceutically acceptable carrier with dissolved oxygen in an amount of equal or less than 2

ppm. Baxter's Epinephrine Bags contain 0.9% sodium chloride in water as an aqueous pharmaceutically acceptable carrier. (Exhibit D (Label) at Section 11.) Atmospheric oxygen "rapidly destroy[s]" epinephrine. (*See* Exhibit A ('719 patent) at 2:3-5.) Thus, for Baxter's Epinephrine Bags to maintain their biologically active R-isomer form and avoid the rapid destruction caused by atmospheric oxygen, on information and belief, Baxter will keep the dissolved oxygen in the water low, including in an amount of equal or less than 2 ppm.

40. Baxter's Epinephrine Bags have a pH of between 3.0 and 4.7. (*See* Exhibit D (Label) at Section 11.)

41. Baxter's Epinephrine Bags contain EDTA, a metal ion chelator selected from the group consisting of EDTA, EGTA, and diethylenetriaminepentaacetic acid, in the composition at a concentration of between about 1 and 50 µg/mL. (*See* Exhibit D (Label) at Section 11.)

42. On information and belief, Baxter's Epinephrine Bags are packaged under an inert gas. Baxter's Epinephrine Bags are sterile. (*See* Exhibit D (Label) at Section 11.) On information and belief, Baxter achieves sterility of Baxter's Epinephrine Bags by packing the Epinephrine Bags under an inert gas.

43. Baxter's Epinephrine Bags are sterilized. (*See* Exhibit D (Label) at Section 11.)

44. Baxter's Epinephrine Bags are substantially antioxidant-free. Baxter's Epinephrine Bags contain 0.05 mg/mL of sodium metabisulfite, an antioxidant, *see* Exhibit D (Label) at Section 11. The '719 patent specification discusses that antioxidant-free compositions "do not include antioxidants in an amount effective to reduce degradation of total epinephrine by at least about 1% when stored over a period of at least three months at 25° C. +/- 2° C" and that this is "equal or less than about 0.01 wt%." (Exhibit A ('719 patent) at 8:7-15.) 0.05 mg/mL of

sodium metabisulfite is equal or less than 0.01 wt%. Thus, Baxter's Epinephrine Bags are substantially antioxidant-free.

45. On information and belief, Baxter's Epinephrine Bags, when stored for at least one month, have total impurities of equal or less than 0.7%. Baxter's Epinephrine Bags are shelf-stable for 12 months. (*See* Exhibit E (Approval Letter) at 2.) On information and belief, Baxter's Epinephrine Bags, once stored for at least one month, should have no more than 4% S-isomer content, at least because epinephrine is only biologically active in the R-isomer, and the S-isomer is biologically inactive. (*See* Exhibit A ('719 patent) at 2:1-2.) Thus, to achieve the dosage strengths described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer. ICH guidance regarding impurities in new drug products provides that the threshold above which a given degradation product must be reported is 0.05% for drug substances, such as epinephrine, having a maximum daily dose of greater than 1 g. Moreover, impurities can lead to patient complications, which, on information and belief, Baxter would avoid.

46. Endo is entitled to a judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Baxter's Epinephrine Bags, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's Epinephrine Bags before expiration of the '719 patent by Baxter or its agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '719 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Endo will be irreparably harmed if Baxter is not enjoined from infringing, inducing, or contributing to infringement of the '719 patent. Endo does not have an adequate remedy at law to fully compensate Endo for its damages.

48. Baxter's infringement of the '719 patent is willful, entitling Endo to enhanced damages. On information and belief Baxter had knowledge of the '719 patent at least as early as July 27, 2021, when the '719 patent issued. Baxter therefore knew that Baxter's Epinephrine Bags would infringe the '719 patent at least as early as July 27, 2021.

49. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '280 PATENT)

50. Endo re-alleges and incorporates Paragraphs 1-30 as if fully set forth herein.

51. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case of controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

53. On information and belief, Baxter will engage immediately and imminently in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Baxter's Epinephrine Bags which will constitute infringement of at least claim 1 of the '280 patent, both directly under 35 U.S.C. § 271(a) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

54. Claim 1 of the '280 patent reads as follows:

> A method of producing a sterile and storage stable ready-to-inject epinephrine composition, comprising:

> combining an aqueous pharmaceutically acceptable carrier with epinephrine and a metal ion chelator such that the epinephrine has a concentration of equal or less than 0.07 mg/ml, wherein the metal ion chelator is present in the composition at a concentration of between about 1 and 50 ug/ml, and wherein substantially all of the epinephrine is an R-isomer;
>
> adjusting the pH of the ready-to-inject epinephrine composition to a pH of between 3.5-4.7;
>
> packaging the ready-to-inject epinephrine composition into a container under an inert gas; and
>
> autoclaving the ready-to-inject epinephrine composition to sterility, wherein sterilization increases S-isomer content to no more than 4%.

55. Baxter's Epinephrine Bags are sterile and storage stable ready-to-inject epinephrine compositions, produced by Baxter or for Baxter. (*See* Exhibit D (Label) at Section 2.1; Exhibit E (Approval Letter) at 2.)

56. Baxter's Epinephrine Bags contain an aqueous pharmaceutically acceptable carrier with epinephrine such that the epinephrine in the ready-to-inject epinephrine composition is at a concentration of equal or less than 0.07 mg/mL. (*See* Exhibit D (Label) at Section 11.)

57. Baxter's Epinephrine Bags contain a metal ion chelator (EDTA) in the composition, which is present in the composition at a concentration of between about 1 and 50 ug/mL. (*See* Exhibit D (Label) at Section 11.)

58. On information and belief, Baxter's Epinephrine Bags contain epinephrine wherein substantially all of the epinephrine is an R-isomer. Baxter's Epinephrine Bags contain 64 µg/mL epinephrine. (*See* Exhibit D (Label) at Section 11.) Baxter's Epinephrine Bags are USP compliant. (*See* Exhibit D (Label) at Section 11; Exhibit E (Approval Letter) at 3.) The USP monograph for epinephrine requires an epinephrine assay of 90-115%. Epinephrine is only

biologically active in the R-isomer, and the S-isomer is biologically inactive. (*See* Exhibit B ('280 patent) at 2:1-3.) To achieve the dosage strength described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer.

59. Baxter's Epinephrine Bags have a pH of between 3.5 and 4.7. (*See* Exhibit D (Label) at Section 11.)

60. On information and belief, Baxter's Epinephrine Bags are packaged under an inert gas. Baxter's Epinephrine Bags are sterile. (*See* Exhibit D (Label) at Section 11.) On information and belief, Baxter achieves sterility of Baxter's Epinephrine Bags by packing the Epinephrine Bags under an inert gas.

61. On information and belief, Baxter's Epinephrine Bags are autoclaved to sterility, wherein sterilization results in S-isomer content to no more than 4%. Baxter's Epinephrine Bags are sterile. (*See* Exhibit D (Label) at Section 11.) One such method of sterilization is autoclaving. (*See, e.g.*, Exhibit B ('280 patent) at 2:65-66.) Baxter's product is USP compliant. (*See* Exhibit D (Label) at Section 11; Exhibit E (Approval Letter) at 3.) The USP monograph for epinephrine requires an epinephrine assay of 90-115%. Further, epinephrine is only biologically active in the R-isomer, and the S-isomer is biologically inactive (Exhibit B ('280 patent) at 2:1-3), thus to achieve the dosage strengths described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer and minimize the amount of biologically inactive S-isomer.

62. Baxter's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Baxter's Epinephrine Bags constitutes infringement of at least claim 10 of the '280 patent, both directly under 35 U.S.C. § 271(a) and

indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

63. Claim 10 of the '280 patent reads as follows:

> A sterile storage stable ready-to-inject epinephrine composition, comprising:
>
> an aqueous pharmaceutically acceptable carrier containing epinephrine and a metal ion chelator;
>
> wherein the epinephrine is present at a concentration of equal or less than 0.07 mg/ml, wherein substantially all of the epinephrine is an R-isomer, and wherein the composition has a pH of between 3.5-4.7;
>
> wherein the ready-to-inject epinephrine composition is substantially antioxidant-free; and
>
> wherein the ready-to-inject epinephrine composition has, after storage of at least one month at 25° C., total impurities of equal or less than 0.7% and equal or less than 4% S-isomer content.

64. Baxter's Epinephrine Bags are storage stable ready-to-inject epinephrine compositions. (*See* Exhibit D (Label) at Section 2.1; Exhibit E (Approval Letter) at 2.)

65. Baxter's Epinephrine Bags contain a metal ion chelator (EDTA) in the composition. (*See* Exhibit D (Label) at Section 11.)

66. Baxter's Epinephrine Bags contain an aqueous pharmaceutically acceptable carrier with epinephrine in an amount such that the epinephrine is present in the ready-to-inject epinephrine composition at a concentration of equal or less than 0.07 mg/mL. (*See* Exhibit D (Label) at Section 11.)

67. On information and belief, Baxter's Epinephrine Bags contain epinephrine wherein substantially all of the epinephrine is an R-isomer. Baxter's Epinephrine Bags contain 64 µg/mL of epinephrine. (*See* Exhibit D (Label) at Section 11.) Baxter's Epinephrine Bags are

USP compliant. (*See* Exhibit D (Label) at Section 11; Exhibit E (Approval Letter) at 3.) The USP monograph for epinephrine requires an epinephrine assay of 90-115%. Epinephrine is only biologically active in the R-isomer, and the S-isomer is biologically inactive. (*See* Exhibit B ('280 patent) at 2:1-3.) To achieve the dosage strength described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer.

68. Baxter's Epinephrine Bags have a pH of between 3.5 and 4.7. (*See* Exhibit D (Label) at Section 11.)

69. Baxter's Epinephrine Bags are substantially antioxidant-free. Baxter's Epinephrine Bags contain 0.05 mg/mL of sodium metabisulfite, an antioxidant, *see* Exhibit D (Label) at Section 11, but the '280 patent specification discusses that antioxidant-free compositions "do not include antioxidants in an amount effective to reduce degradation of total epinephrine by at least about 1% when stored over a period of at least three months at 25° C. +/- 2° C" and that this is "equal or less than about 0.01 wt%." (Exhibit B ('280 patent) at 8:11-19.) 0.05 mg/mL of sodium metabisulfite is equal or less than 0.01 wt%. Thus, Baxter's Epinephrine Bags are substantially antioxidant-free.

70. On information and belief, Baxter's Epinephrine Bags, when stored for at least one month at 25° C, have total impurities of equal or less than 0.7%. Baxter's Epinephrine Bags are shelf-stable for 12 months. (*See* Exhibit E (Approval Letter) at 2.) On information and belief, Baxter's Epinephrine Bags, once stored for at least one month, should have no more than 4% S-isomer content, at least because epinephrine is only biologically active in the R-isomer, and the S-isomer is biologically inactive. (*See* Exhibit B ('280 patent) at 2:1-2.) Thus, to achieve the dosage strength described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer. ICH guidance regarding impurities in

new drug products provides that the threshold above which a given degradation product must be reported is 0.05% for drug substances, such as epinephrine, having a maximum daily dose of greater than 1 g. Moreover, impurities can lead to patient complications, which, on information and belief, Baxter would avoid.

71. Endo is entitled to a judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Baxter's Epinephrine Bags, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's Epinephrine Bags before expiration of the '280 patent by Baxter or its agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '280 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

72. Endo will be irreparably harmed if Baxter is not enjoined from infringing, inducing, or contributing to infringement of the '280 patent. Endo does not have an adequate remedy at law to fully compensate Endo for its damages.

73. Baxter's infringement of the '280 patent is willful, entitling Endo to enhanced damages. Baxter had knowledge of the '280 patent no later than May 10, 2023, when Endo listed the '280 patent in the Orange Book for the Adrenalin® bags product. Baxter therefore knew that Baxter's Epinephrine Bags would infringe the '280 patent no later than May 10, 2023. Baxter also had knowledge of the '280 patent no later than March 4, 2025, when counsel for Endo notified Baxter of the '280 patent.

74. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT III
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '837 PATENT)

75. Endo re-alleges and incorporates Paragraphs 1-30 as if fully set forth herein.

76. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. There is an actual case of controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

78. On information and belief, Baxter will engage immediately and imminently in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Baxter's Epinephrine Bags which will constitute infringement of at least claim 1 of the '837 patent, both directly under 35 U.S.C. § 271(a) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

79. Claim 1 of the '837 patent reads as follows:

> A sterile storage stable ready-to-inject epinephrine composition, comprising:
>
> an aqueous pharmaceutically acceptable carrier containing epinephrine, a tonicity agent, and a metal ion chelator;
>
> wherein the epinephrine is present at a concentration of equal or less than 0.07 mg/ml, and wherein at least about 90 mol % of the epinephrine is an R-isomer;
>
> wherein the composition has a pH of between 3.0-4.7;
>
> wherein the metal ion chelator is a bicarboxylic acid, a tricarboxylic acid, or an aminopolycarboxylic acid;
>
> wherein the metal ion chelator is present in the composition at a concentration of between about 1 and 50 μg/ml; and
>
> wherein the composition has a total impurities concentration of equal to or less than 0.3% after storage of at least one month at 25° C.

80. Baxter's Epinephrine Bags are sterile and storage stable ready-to-inject epinephrine compositions, produced by Baxter or for Baxter. (*See* Exhibit D (Label) at Section 2.1; Exhibit E (Approval Letter) at 2.)

81. Baxter's Epinephrine Bags contain an aqueous pharmaceutically acceptable carrier with epinephrine such that the epinephrine in the ready-to-inject epinephrine composition is at a concentration of equal or less than 0.07 mg/mL. (*See* Exhibit D (Label) at Section 11.)

82. Baxter's Epinephrine Bags contain a tonicity agent, namely sodium chloride. (*See* Exhibit D (Label) at Section 11.)

83. Baxter's Epinephrine Bags contain a metal ion chelator (EDTA) in the composition. (*See* Exhibit D (Label) at Section 11.)

84. On information and belief, Baxter's Epinephrine Bags contain epinephrine wherein at least about 90 mol% of the epinephrine is an R-isomer. Baxter's Epinephrine Bags contain 64 µg/mL of epinephrine. (*See* Exhibit D (Label) at Section 11.) Baxter's Epinephrine Bags are USP compliant. (*See* Exhibit D (Label) at Section 11; Exhibit E (Approval Letter) at 3.) The USP monograph for epinephrine requires an epinephrine assay of 90-115%. Epinephrine is only biologically active in the R-isomer, and the S-isomer is biologically inactive. (*See* Exhibit C ('837 patent) at 2:1-4.) To achieve the dosage strength described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer.

85. Baxter's Epinephrine Bags have a pH of between 3.0 and 4.7. (*See* Exhibit D (Label) at Section 11.)

86. Baxter's Epinephrine Bags contain a metal ion chelator, EDTA, in the composition, which is an aminopolycarboxylic acid, and which is present in the composition at a concentration of between about 1 and 50 ug/mL. (*See* Exhibit D (Label) at Section 11.)

87. On information and belief, Baxter's Epinephrine Bags have a total impurities concentration of equal to or less than 0.3% after storage of at least one month at 25° C. Baxter's Epinephrine Bags are shelf-stable for 12 months. (*See* Exhibit E (Approval Letter) at 2.) ICH guidance regarding impurities in new drug products provides that the threshold above which a given degradation product must be reported is 0.05% for drug substances, such as epinephrine, having a maximum daily dose of greater than 1 g. Moreover, impurities can lead to patient complications, which, on information and belief, Baxter would avoid.

88. Baxter's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Baxter's Epinephrine Bags constitutes infringement of at least claim 10 of the '837 patent, both directly under 35 U.S.C. § 271(a) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

89. Claim 10 of the '837 patent reads as follows:

> A method of producing a sterile and storage stabile ready-to-inject epinephrine composition, comprising:
>
> combining an aqueous pharmaceutically acceptable carrier with epinephrine, a tonicity agent, and metal ion chelator such that the epinephrine has a concentration of equal or less than 0.07 mg/ml;
>
> wherein at least about 90 mol % of the epinephrine is an R-isomer;
>
> wherein the metal ion chelator is a bicarboxylic acid, a tricarboxylic acid, or an aminopolycarboxylic acid; and
>
> wherein the metal ion chelator is present in the composition at a concentration of between about 1 and 50 μg/ml;
>
> adjusting a pH of the ready-to-inject epinephrine composition to between 3.0-4.7;
>
> packaging the ready-to-inject epinephrine composition into a container under an inert gas; and

> autoclaving the ready-to-inject epinephrine composition to sterility, wherein the composition has a total impurities concentration of equal to or less than 0.3% after storage of at least one month at 25° C.

90. Baxter's Epinephrine Bags are storage stable ready-to-inject epinephrine compositions. (*See* Exhibit D (Label) at Section 2.1; Exhibit E (Approval Letter) at 2.)

91. Baxter's Epinephrine Bags contain an aqueous pharmaceutically acceptable carrier with epinephrine in an amount such that the epinephrine is present in the ready-to-inject epinephrine composition at a concentration of equal or less than 0.07 mg/mL. (*See* Exhibit D (Label) at Section 11.)

92. Baxter's Epinephrine Bags contain a tonicity agent, namely sodium chloride. (*See* Exhibit D (Label) at Section 11.)

93. On information and belief, Baxter's Epinephrine Bags contain epinephrine wherein at least 90 mol % of the epinephrine is an R-isomer. Baxter's Epinephrine Bags contain 64 µg/mL of epinephrine. (*See* Exhibit D (Label) at Section 11.) Baxter's Epinephrine Bags are USP compliant. (*See* Exhibit D (Label) at Section 11; Exhibit E (Approval Letter) at 3.) The USP monograph for epinephrine requires an epinephrine assay of 90-115%. Epinephrine is only biologically active in the R-isomer, and the S-isomer is biologically inactive. (*See* Exhibit C ('837 patent) at 2:1-4.) To achieve the dosage strength described, on information and belief, Baxter's Epinephrine Bags will maximize the amount of biologically active R-isomer.

94. Baxter's Epinephrine Bags contain a metal ion chelator, EDTA, in the composition, which is an aminopolycarboxylic acid, and which is present in the composition at a concentration of between about 1 and 50 ug/mL. (*See* Exhibit D (Label) at Section 11.)

95. Baxter's Epinephrine Bags have a pH of between 3.0 and 4.7. (*See* Exhibit D (Label) at Section 11.)

96. On information and belief, Baxter's Epinephrine Bags are packaged under an inert gas. Baxter's Epinephrine Bags are sterile. (*See* Exhibit D (Label) at Section 11.) On information and belief, Baxter achieves sterility of Baxter's Epinephrine Bags by packing the Epinephrine Bags under an inert gas.

97. On information and belief, Baxter's Epinephrine Bags are autoclaved to sterility, wherein sterilization results in S-isomer content to no more than 4%. Baxter's Epinephrine Bags are sterile. (*See* Exhibit D (Label) at Section 11.) One such method of sterilization is autoclaving. (*See, e.g.*, Exhibit C ('837 patent) at 2:66-67.)

98. On information and belief, Baxter's Epinephrine Bags, when stored for at least one month at 25° C, have total impurities of equal or less than 0.3%. Baxter's Epinephrine Bags are shelf-stable for 12 months. (*See* Exhibit E (Approval Letter) at 2.) ICH guidance regarding impurities in new drug products provides that the threshold above which a given degradation product must be reported is 0.05% for drug substances, such as epinephrine, having a maximum daily dose of greater than 1 g. Moreover, impurities can lead to patient complications, which, on information and belief, Baxter would avoid.

99. Endo is entitled to a judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Baxter's Epinephrine Bags, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's Epinephrine Bags before expiration of the '837 patent by Baxter or its agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '280 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

100. Endo will be irreparably harmed if Baxter is not enjoined from infringing, inducing, or contributing to infringement of the '837 patent. Endo does not have an adequate remedy at law to fully compensate Endo for its damages.

101. Baxter's infringement of the '837 patent is willful, entitling Endo to enhanced damages. Baxter had knowledge of the '837 patent no later than November 6, 2024, when Endo listed the '837 patent in the Orange Book for the Adrenalin® bags product. Baxter therefore knew that Baxter's Epinephrine Bags would infringe the '837 patent no later than November 6, 2024. Baxter also had knowledge of the '837 patent no later than March 4, 2025, when counsel for Endo notified Baxter of the '837 patent.

102. This case is exceptional and Endo is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A declaration under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale, and/or importation of Baxter's Epinephrine Bags before the expiration of the Patents-In-Suit does and will infringe one or more claims of the Patents-in-Suit.

B. A judgment declaring that Baxter has infringed directly and indirectly one or more claims of the '719 patent, and Baxter's manufacture, use, sale, offer for sale and/or importation of Baxter's Epinephrine Bags infringe one or more claims of the '719 patent;

C. A judgment permanently enjoining Baxter, its officers, agents, servants and employees, and those in active concert or participation with any of them, from infringing the '719 patent either directly or indirectly;

D. An award of compensatory damages to Endo for Baxter's infringement of the '719 patent;

E. An award of increased damages to Endo under 35 U.S.C. § 284 for Baxter's willful and deliberate infringement of the '719 patent;

F. A judgment declaring that Baxter has infringed directly and indirectly one or more claims of the '280 patent, and Baxter's manufacture, use, sale, offer for sale and/or importation of Baxter's Epinephrine Bags infringe one or more claims of the '280 patent;

G. A judgment permanently enjoining Baxter, its officers, agents, servants and employees, and those in active concert or participation with any of them, from infringing the '280 patent either directly or indirectly;

H. An award of compensatory damages to Endo for Baxter's infringement of the '280 patent;

I. An award of increased damages to Endo under 35 U.S.C. § 284 for Baxter's willful and deliberate infringement of the '280 patent;

J. A judgment declaring that Baxter has infringed directly and indirectly one or more claims of the '837 patent, and Baxter's manufacture, use, sale, offer for sale and/or importation of Baxter's Epinephrine Bags infringe one or more claims of the '837 patent;

K. A judgment permanently enjoining Baxter, its officers, agents, servants and employees, and those in active concert or participation with any of them, from infringing the '837 patent either directly or indirectly;

L. An award of compensatory damages to Endo for Baxter's infringement of the '837 patent;

M. An award of increased damages to Endo under 35 U.S.C. § 284 for Baxter's willful and deliberate infringement of the '837 patent;

N. A judgment declaring this to be an exceptional case under 35 U.S.C. § 285 in Endo's favor and awarding Endo its reasonable attorneys' fees;

O. An award of Endo's costs and expenses for defending this action, together with pre-judgment and post-judgment interest; and

P. An award to Endo of such other and further relief as the Court may deem just and proper.

Dated: March 5, 2025

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